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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SPRING PHARMACEUTICALS, LLC, Plaintiff, v. RETROPHIN, INC., MARTIN SHKRELI, MISSION PHARMACAL COMPANY, and ALAMO PHARMA SERVICES, INC., Defendants.	)	18 4553 Case No. _____

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

NOW COMES Plaintiff Spring Pharmaceuticals, LLC ("Spring" or "Plaintiff"), by and through its undersigned counsel, and for its Complaint against Defendants Retrophin, Inc. ("Retrophin"), Martin Shkreli ("Shkreli"), Mission Pharmacal Company ("Mission"), and Alamo Pharma Services, Inc. ("Alamo") (collectively, "Defendants"), states as follows:

NATURE OF THE ACTION

1. This is an action for damages and permanent injunctive relief against Defendants for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and state antitrust, unfair competition, and unjust enrichment pursuant to the common laws of the State of Pennsylvania.

2. Since 2014, Defendants have established and maintained an unlawful monopoly over Thiola, a prescription pharmaceutical product used to treat patients suffering from a chronic genetic disease known as cystinuria, which causes recurring kidney stones. The active ingredient in Thiola is tiopronin. Thiola is the only currently available tiopronin product approved by the federal Food and Drug Administration ("FDA"), and is not covered by any patents or regulatory exclusivities. Despite being off-patent, Thiola has not yet been subjected to generic

competition—precisely because Defendants' exclusionary and unlawful conduct has prevented such competition. As detailed herein, since 2014, Defendants have acted in concert to manufacture and distribute Thiola on a direct-to-patient basis, a scheme designed to preclude generic entry and to preserve monopoly power in violation of federal and state antitrust laws.

3. As a result of Defendants' unlawful conduct, Plaintiff—a pharmaceutical company desiring to bring a lower-cost, competing generic version of Thiola to market—has been unable to access samples of Thiola to perform the testing required by the FDA, and has thereby been excluded from the marketplace. Defendants, meanwhile, have been able to set and preserve monopoly-level prices, leaving patients, health care payors, and taxpayers to suffer the effects of Defendants' illegal monopoly.

4. This unlawful monopoly was initially implemented by Defendant Martin Shkreli, the founder and original CEO of Retrophin. Under Shkreli's leadership, Retrophin's business model was to acquire off-patent, sole-source drugs, move the drugs into a restricted distribution system designed to prevent generic entry, and raise their prices by staggering amounts.

5. Media reports on Thiola and other extraordinary price hikes on off-patent pharmaceutical products led to bipartisan congressional investigations by both the House of Representatives and the Senate. In December 2016, following its investigation, the Senate produced a 130-page report, entitled, "*Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*" (the "Senate Report").[1]

[1] The Senate Report is attached hereto as Exhibit A ("Ex. A"), and select exhibits referenced therein are attached hereto as Exhibit B ("Ex. B"). Exhibits A and B are incorporated as part of the Complaint. The full compendium of public exhibits to the Senate Report is available at: *Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model*, U.S. SENATE SPECIAL COMM. ON AGING (Mar. 17, 2016), https://www.aging.senate.gov/hearings/sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model.

6. As evidenced by the Senate Report and other public documents, Thiola is a prime example of Shkreli and Retrophin's monopolistic business model at work, in concert with Defendants Mission and Alamo.

7. Mission, a pharmaceuticals manufacturer, brought Thiola to market in the late 1980s. In May 2014, however, Mission entered into an agreement with Retrophin, pursuant to which Retrophin obtained an exclusive license to market, sell, and commercialize Thiola in the United States. In exchange, Mission received a $3 million up-front payment, a guaranteed royalty tied to product sales, and additional compensation through the employment of its sales-force subsidiary, Alamo.

8. Shortly after acquiring the rights to Thiola, Retrophin implemented its unlawful business plan: it removed the product from pharmacy shelves and moved Thiola into a closed distribution system—a strategy intended to "prevent[] generics from accessing the product[.]"[2] Today, Thiola is only available through a single specialty pharmacy under Retrophin's careful watch. This distribution scheme thwarts generic competition by ensuring that generic manufacturers cannot access sufficient quantities of Thiola necessary to conduct what is known as "bioequivalence" testing—that is, testing required by the FDA to confirm that a generic version of an approved brand product is equivalently effective and safe for human use.

9. After acquiring exclusive rights to Thiola and moving it into a closed distribution system, Retrophin proceeded to spike the price of Thiola—a product Retrophin touted publicly as "an incredible medicine for people suffering from cystinuria" and "the standard of care for this disease."[3] Indeed, shortly after Retrophin acquired the rights to Thiola, a pharmaceutical

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[2] Ex. B, Senate Report Hr'g Ex. 18 at 8.

[3] Ex. B, Senate Report Hr'g Ex. 1 at 1.

product that first went on the market in 1988, Retrophin increased its price from $1.50 a tablet to $30 per tablet—***an increase of nearly 2,000%***.

10. Internal documents showcase Retrophin's intent to exclude generic competitors and to price gouge the American public. In a May 3, 2014 email exchange with an investor, for example, Shkreli was candid about his motivation for acquiring Thiola: "The next generation of pharma guys (or the smart ones) understand the inelasticity of certain products. . . . We'd pay $1m to acquire a drug called Thiola, which is the only treatment for a rare disease called cystinuria . . . . The drug does $1.2m in sales. It is woefully underpriced and would not stop selling at orphan prices. With new pricing we estimate sales of $20 to $40 million. Almost 95% EBITDA margins . . . . A ***$100m present for you this morning***."[4]

11. With its investors, Retrophin was candid about the purpose of its restricted distribution system, highlighting it in one May 2014 presentation: "Closed distribution system ***prevents generics from accessing the product for bioequivalence studies***."[5] The company was equally blunt during its May 30, 2014 conference call announcing the Thiola deal: "We do not sell Retrophin products to generic companies."[6] Retrophin further noted, "The whole model that generics rely upon is turned upside down with specialty pharmacy distribution."[7]

12. Retrophin's rationale is clear: by preventing generics from purchasing samples necessary to conduct required testing, it precludes generics from entering the market at all—preserving its ability to set monopoly prices and reap supracompetitive profits from the sales of a vital health product.

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[4] Ex. B, Senate Report Hr'g Ex. 10 at 1-2 (emphasis added).

[5] Ex. B, Senate Report Hr'g Ex. 18 at 8 (emphasis added).

[6] Ex. B, Senate Report Hr'g Ex. 1 at 3 (emphasis added).

[7] *Id.*

13. After Shkreli left Retrophin in October 2014, Retrophin, Mission, and Alamo continued to use—and profit from—the exclusive licensing agreement and restricted distribution scheme designed to prevent generic competition. Indeed, each of Retrophin, Mission, and Alamo has refused to sell samples of Thiola to Plaintiff, even at market price, and has thereby prevented Plaintiff from conducting FDA-required studies and entering the marketplace.

14. Unless it is enjoined, this unlawful arrangement by and among the Defendants will extend at least through 2029, by virtue of the most recent contract amendment.[8]

15. Since at least May 2014, Defendants' exclusive and anticompetitive scheme has worked to benefit Defendants and to injure generics and consumers alike: there is no generic version of Thiola on the market. This illegal scheme has continued through the present day.

16. Defendants' anticompetitive agreement and conduct unreasonably restrain trade without legitimate justification or pro-competitive benefits, violating both federal and state antitrust laws.

17. As a result of Defendants' unfair and anticompetitive business practices, Plaintiff has suffered, and continues to suffer, competitive and commercial injuries. Consumers, too, have suffered from the lack of generic price competition—injuries squarely within the purview of antitrust law. Plaintiff now seeks injunctive and monetary relief to redress these injuries.

PARTIES

18. Plaintiff Spring Pharmaceuticals, LLC is a Virginia limited liability company with its principal place of business in McLean, Virginia.

19. Defendant Retrophin, Inc. is a publicly traded corporation organized under the laws of the State of Delaware, with its principal place of business in San Diego, California.

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[8] *See Retrophin Reports Third Quarter 2017 Financial Results*, RETROPHIN (Nov. 7, 2017), http://ir.retrophin.com/news-releases/news-release-details/retrophin-reports-third-quarter-2017-financial-results.

Retrophin sells three drugs, including Thiola. Martin Shkreli, then CEO of Retrophin, and others negotiated the subject Trademark License & Supply Agreement, dated May 29, 2014 (the "Agreement"), while working for Retrophin in New York, New York.

20. Defendant Martin Shkreli, an incarcerated individual, resides in New Jersey at the Fort Dix Federal Correctional Institution following his August 2017 conviction on securities fraud charges. Prior to his incarceration, Shkreli was domiciled in New York. Defendant Shkreli signed the Agreement on behalf of Retrophin.

21. Defendant Mission Pharmacal Company is a corporation organized under the laws of the State of Texas, with its principal place of business in San Antonio, Texas. Mission's "Commercial Office" is located at 77 N. Broad Street, Doylestown, Pennsylvania. Mission's Vice President of Corporate Business Development, located in Doylestown, Pennsylvania, negotiated the Agreement on behalf of Mission.

22. Defendant Alamo Pharma Services, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 77 N. Broad Street, Doylestown, Pennsylvania. Alamo is a wholly-owned subsidiary of Mission and provides exclusive sales services to Retrophin under the Agreement.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. Additionally, pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over Plaintiff's state law claim, which arises from the same set of facts, and forms part of the same case or controversy, as its federal claims.

24. This Court has personal jurisdiction over Defendant Mission under 42 Pa. Cons. Stat. §§ 5301, 5322 and 15 U.S.C. § 22. Mission has engaged in systematic, purposeful, and continuous contacts in this judicial district. Mission's commercial office is located in this judicial district and, on information and belief, Mission transacts business by, among other things, offering to sell, selling, and shipping pharmaceutical products including Thiola into or through this judicial district.

25. This Court has personal jurisdiction over Defendant Alamo under 42 Pa. Cons. Stat. § 5301 and 15 U.S.C. § 22. Alamo is a corporation with its principal place of business in this judicial district, and is registered to transact business in Pennsylvania as a foreign corporation. On information and belief, Alamo transacts business by, among other things, offering to sell and selling pharmaceutical products including Thiola throughout this judicial district.

26. This Court has personal jurisdiction over Defendant Retrophin under 42 Pa. Cons. Stat. §§ 5301, 5322 and 15 U.S.C. § 22. Retrophin is registered to transact business in Pennsylvania as a foreign corporation, and has been approved by the Pennsylvania Department of Human Services as a participating drug company in the State's Medical Assistance Program. On information and belief, Retrophin transacts business by, among other things, offering to sell and selling pharmaceutical products including Thiola throughout this judicial district.

27. This Court has personal jurisdiction over Defendant Shkreli under 42 Pa. Cons. Stat. § 5322. Shkreli, among other things, negotiated and contracted with a Pennsylvania-based representative of Mission to supply, offer to sell, and sell pharmaceuticals in Pennsylvania, thereby causing anticompetitive harm in this judicial district.

28. A substantial part of the events giving rise to the claims asserted in this Complaint took place in this judicial district. For example, Mission's business development representative negotiated and finalized the Agreement from his office in Doylestown, Pennsylvania.[9] This exclusive contract led to, and is in substantial furtherance of, the complained-of misconduct. Plaintiff also requested Thiola samples from Alamo's Doylestown, Pennsylvania office, and was denied those samples. On information and belief, certain Retrophin employees responsible for promoting Thiola are Pennsylvania residents. Thiola is listed on Pennsylvania's Medicare formulary and, on information and belief, patients located in the State of Pennsylvania are prescribed and use Thiola. On information and belief, doctors in Pennsylvania have received payments from Defendants Retrophin and Mission related to the promotion of Defendants' products. Moreover, Defendants Alamo, Mission, and Retrophin are found in and/or transact business in this district. Each Defendant is subject to personal jurisdiction in this judicial district. Venue is therefore proper in the Eastern District of Pennsylvania pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

FACTUAL BACKGROUND

Statutory and Regulatory Background: Generic Competition

29. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act") to ensure the availability of low-cost generic drugs for millions of Americans, recognizing the benefit of generic competition with respect to patient care and consumer savings. *See* 21 U.S.C. § 355(j).

30. Specifically, Congress authorized an expedited procedure for FDA approval of generic drugs, eliminating the need for a firm seeking to market a generic version of a brand

[9] Ex. B, Senate Report Hr'g Ex. 17 at 1 (Email from Jim Self, Vice President of Corp. Bus. Dev., Mission, to Martin Shkreli, CEO, Retrophin (May 30, 2014) ("At Mission we have a [Business Development] team of 1")).

manufacturer's product to conduct lengthy and expensive clinical trials to demonstrate its product's safety and efficacy. Instead, under the Hatch-Waxman Act, the generic firm may rely on the FDA's previous finding of safety and effectiveness with respect to the brand product—so long as the firm is able to demonstrate that the proposed generic is biologically equivalent to, and has the same active ingredients, route of administration, dosage form, strength, labeling, and conditions of use as, that brand drug. *See id.* §§ 355(j)(2)(A)(i)–(v).

31. Under the governing statute, "[a] drug shall be considered to be bioequivalent to a listed drug" only if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses[.]" *See id.* § 355(j)(8)(B)(i). The "listed drug," in turn, refers to the particular FDA-approved brand drug at issue. *See id.* § 355(j)(7).

32. This means that generic manufacturers ***must obtain samples of the brand product*** in order to conduct FDA-required bioequivalence studies before being approved for the United States market. According to the FDA, "[g]eneric manufacturers need anywhere from 2,000 to 5,000 doses of the branded drug in order to run studies to prove their generic medicine is the same as the branded drug."[10]

33. In June 2017, in an effort to promote generic competition, the FDA began publishing a list of off-patent, off-exclusivity brand products without approved generics, including tiopronin (Thiola).[11] Shortly thereafter, in July 2017, the FDA issued draft guidance

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[10] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency actions to further deter 'gaming' of the generic drug approval process by the use of citizen petitions*, U.S. FOOD & DRUG ADMIN. (Oct. 2, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252.htm.

[11] *FDA Tackles Drug Competition to Improve Patient Access*, U.S. FOOD & DRUG ADMIN. (June 27, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm; *see also List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. 10 (Apr. 13, 2018),

on the testing required to seek approval for a generic version of Thiola. Specifically, the guidance requires, *inter alia*, a generic applicant to "[c]onduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference product [*i.e.*, Thiola]."[12] Absent samples of Thiola, the necessary dissolution testing cannot be undertaken.

34. Usually, a generic manufacturer can purchase adequate amounts of the brand product for bioequivalence testing through normal distribution channels, such as through distributors, wholesalers, or pharmacies.

35. Then, once the generic manufacturer demonstrates bioequivalence and secures regulatory approval, including an "AB" rating from the FDA—a designation conveying that the generic alternative has satisfied bioequivalence standards—the generic version becomes subject to "automatic substitution" laws in effect in most states, including Pennsylvania. These substitution laws require or allow pharmacists to substitute the AB-rated generic version of a product for the brand product, unless the prescribing physician specifically requests otherwise.

36. However, when manufacturers of off-patent, branded products remove their products from normal distribution channels and block the sale of samples to would-be generic competitors, they undermine the very purpose of the Hatch-Waxman Act.

37. The Hatch-Waxman process, as described above, was designed "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012). Generic firms are typically able to offer lower prices than brand manufacturers because they do not need to replicate the brand manufacturers' costly and time-consuming clinical trials. Recent FDA analysis, for example, has confirmed the association

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https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM564441.pdf.

[12] *Draft Guidance on Tiopronin*, U.S. FOOD & DRUG ADMIN. 1 (Jul. 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM566424.pdf

between generic competition and lower prices, demonstrating that price reductions start with the first generic entrant.[13] The Government Accountability Office has reached the same conclusion, noting in one recent report that, "[o]n average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug."[14] As a result, the Federal Trade Commission ("FTC") has acknowledged, "there are . . . few things more effective in lowering the cost of prescription drugs than fostering substantial generic entry upon patent expiration, and letting competitive markets drive prices ever lower."[15]

38. Generics result in significant patient and taxpayer savings. According to one recent industry report, in 2017, generics generated a total of $265 billion in savings in the United States, including $82.7 billion in Medicare savings and $40.6 billion in Medicaid savings.[16]

39. The Hatch-Waxman process described above is a congressionally mandated counterbalance between access and innovation—encouraged through exclusivity and patent periods—that remains a cornerstone of federal drug regulation today.

40. Gamesmanship by brand manufacturers, though, threatens this very structure. The FDA, for example, has recently noted a pattern of "unfair and exploitative practices" by brand manufacturers "to frustrate or block the sale of a branded drug to a generic firm[,]"[17]

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[13] *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN. (Nov. 28, 2017), https://www.fda.gov/aboutfda/ centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm.

[14] John E. Dicken, *Drug Pricing: Research on Savings from Generic Drug Use*, U.S. GOV'T ACCOUNTABILITY OFFICE 1 (Jan. 31, 2012), https://www.gao.gov/assets/590/588064.pdf.

[15] Maureen Ohlhausen, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Workshop*, FED. TRADE COMM'N 3-4 (Nov. 8, 2017), https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-intro-keynote-remarks/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_1.pdf ("Understanding Competition in Prescription Drug Markets").

[16] *Generic Drug Access & Savings in the U.S.: Access in Jeopardy*, ASS'N FOR ACCESSIBLE MEDS. 4 (2018), https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf.

[17] *Remarks by Dr. Gottlieb at the FTC*, U.S. FOOD & DRUG ADMIN. (Nov. 8, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm.

despite that a "path to securing samples of brand drugs for the purpose of generic drug development should always be available" in order to "improve access and affordability."[18] As the Commissioner of the FDA acknowledged as recently as October 2, 2018, these "anticompetitive techniques" upset "the careful balance that Congress sought between product innovation and access."[19]

41. The FTC has also recognized the antitrust implications of when "[s]ome pharmaceuticals lose patent protection, but then draw no generic entry, allowing the incumbent firm to maintain high prices[,]" or when "speculators have [bought] up off-patent, single-source drugs and raised prices dramatically without drawing an immediate competitive response."[20]

Defendants' Anticompetitive Business Practices

42. Defendants here have engaged in exclusionary practices that undermine the pathway to generic approval under the Hatch-Waxman process.

43. Defendant Shkreli, previously a hedge fund manager, founded Retrophin in March 2011 and served as its CEO until October 2014. Retrophin describes itself as a pharmaceutical company focused "on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients."[21] As detailed herein, however, Retrophin's true focus is on three things: first, acquiring off-patent, decades-old pharmaceutical products with no intention to

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[18] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition*, U.S. FOOD & DRUG ADMIN. (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

[19] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency actions to further deter 'gaming' of the generic drug approval process by the use of citizen petitions*, U.S. FOOD & DRUG ADMIN. (Oct. 2, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252.htm.

[20] Understanding Competition in Prescription Drug Markets at 4.

[21] *Retrophin Accounts Agreement to Acquire Manchester Pharmaceuticals*, RETROPHIN (Feb. 12, 2014), http://ir.retrophin.com/news-releases/news-release-details/retrophin-announces-agreement-acquire-manchester-pharmaceuticals.

invest in research and development; second, moving the products into a closed distribution system designed to prevent generic competition; and third, re-pricing the products to reap supracompetitive profits at the expense of patient health and consumer welfare.

44. Under Shkreli's leadership, Retrophin applied this business model to multiple commercial acquisitions. In February 2014, for example, Retrophin acquired non-party Manchester Pharmaceuticals LLC, a specialty pharmaceutical company focused on rare disease treatment. With this acquisition, Retrophin acquired the rights to Chenodal®, an FDA-approved pharmaceutical product.

45. In an investor presentation dated February 13, 2014, Retrophin touted Chenodal as an effective treatment for gallstones as well as the "standard of care" for CTX, a rare genetic disorder that—"without Chenodal treatment"—"can be lethal[.]"[22] Retrophin was unequivocal about its distribution plans for the drug—it quickly moved to a "[c]entric specialty pharmacy distributor" model, wherein "[abbreviated new drug application] filings are impossible unless generic company illegally penetrates specialty distributor [model]." This closed distribution system, as Retrophin frankly noted, "***does not allow for generics to access product for bioequivalence study***."[23]

46. Retrophin further highlighted its plans to employ a "specialty salesforce with a targeted commercial footprint."[24]

47. Retrophin's business model—closed distribution and specialty sales—created an artificial monopoly that allowed Retrophin to profit from price gouging. As Shkreli later boasted

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[22] Ex. B, Senate Report Hr'g Ex. 3 at 5-7.

[23] *Id.* at 12 (emphasis added).

[24] Ex. B, Senate Report Hr'g Ex. 59 at 2.

on a presentation slide entitled "Track Record of Successful Transactions," Retrophin "[i]ncreased Chenodal price 5x with no pushback from payors."[25]

48. Under Shkreli's direction, Retrophin replicated this same business model with respect to Thiola—with an even greater price increase.

49. According to emails produced in connection with the Senate investigation, a member of Retrophin's business development team "discovered the Thiola opportunity," which Shkreli saw as "very simple and Manchester [Pharmaceuticals] like."[26] On May 3, 2014, while the deal was "still a medium stage negotiation and may not come to fruition," Shkreli described the opportunity to an investor as follows: "We'd pay $1m to acquire a drug called Thiola, which is ***the only treatment for a rare disease called cystinuria*** . . . . The drug does $1.2m in sales. It is woefully underpriced and would not stop selling at orphan prices. With new pricing we estimate sales of $20 to $40 million. Almost 95% EBITDA margins . . . . A ***$100m present for you this morning***."[27]

50. Less than one month later, the licensing deal was done. As Jim Self—Mission's Vice President of Corporate Business Development—noted in a May 30, 2014 email to Shkreli, "This was seriously the fastest I've ever seen these types of deals get done. Nice job of removing the minutia and keeping the rails greased."[28]

51. In terms of deal mechanics, Retrophin acquired an exclusive license to market, sell, and commercialize Thiola in the United States pursuant to the Agreement. In exchange,

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[25] *Id.*

[26] Ex. B, Senate Report Hr'g Ex. 1 at 3; Ex. B, Senate Report Hr'g Ex. 10 at 2.

[27] Ex. B, Senate Report Hr'g Ex. 10 at 2 (emphasis added).

[28] Ex. B, Senate Report Hr'g Ex. 17 at 1.

Mission received an upfront license fee of $3 million, in addition to guaranteed minimum royalties each year of $2 million or 20% of net sales.[29]

52. The Agreement also required Retrophin to appoint Alamo, Mission's Pennsylvania-based subsidiary, as the "exclusive provider of sales force services" pursuant to an incorporated "Master Services Agreement," providing Mission an additional form of compensation under the exclusive deal.

53. Retrophin's documents and public filings reveal the integral and ongoing role that Alamo and Mission played (and continue to play) in Retrophin's business scheme. Alamo, for example, is referred to in Retrophin's documents as both "Mission's contract sales force business" and the "Retrophin nephrology/urology sales force"—a key piece of Retrophin's revenue-growth strategy.[30] Mission, meanwhile, is referred to as Retrophin's "great partner," with whom Retrophin planned—as early as May 2014—to develop a higher-dosage Thiola formulation to replace the existing, off-patent 100mg tablet.[31]

54. After acquiring the rights to Thiola, Retrophin moved the drug into closed distribution, candidly acknowledging in its Thiola-licensing investor call from May 2014: "We do not sell Retrophin products to generic companies. . . . The specialty pharmacy distribution model takes the AB substitutable rating that generics get and neuters it. . . . This whole model that generics rely upon is turned upside down[.]"[32]

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[29] Retrophin, Inc., Annual Report 8 (Form 10-K) (Mar. 11, 2015).

[30] Ex. B, Senate Report Hr'g Ex. 15 at 2; Ex. B, Senate Report Hr'g Ex. 18 at 9.

[31] Ex. B, Senate Report Hr'g Ex. 1 at 2-3 ("With our partner Mission, . . . [o]ur intent is to remove our legacy products from the channel as soon as new products are available, which is often called a 'hard switch'").

[32] Ex. B, Senate Report Hr'g Ex. 1 at 3 (emphasis added). As described above, "AB substitutable" refers to generic drugs that have been approved by the FDA as bioequivalent to a brand drug and thus subject to states' generic substitution laws, which require or allow pharmacists to substitute the AB-rated generic version for brand products, unless the prescribing physician specifically requests otherwise.

55. Retrophin was equally blunt in its investor presentation from May 2014: "Similar to Chenodal, Retrophin will place Thiola into closed distribution. ***Closed distribution system prevents generics from accessing the product for bioequivalence studies***."[33]

56. Specifically, under its exclusive license, Retrophin appointed a Wisconsin-based specialty pharmacy as the exclusive distributor of Thiola in the United States. This entity acts as the exclusive "pharmacy" for patients and healthcare providers seeking Thiola. Both in intent and effect, this closed distribution system precludes sales of Thiola to generic manufacturers such as Plaintiff.

57. Protected from competition by its exclusive license and closed distribution system, Retrophin then significantly raised the price of Thiola. Indeed, despite acknowledging publicly that Thiola is the "standard of care" for cystinuria and promising to "understand the plight of patients who are abandoned by the pharmaceutical industry,"[34] Retrophin turned around and instituted an immediate price hike in accordance with Shkreli's drug pricing philosophy: "[d]rugs are typically non-discretionary and consumers are relatively price insensitive . . . . ***Exclusivity (closed distribution) creates a barrier and pricing power***."[35]

58. Specifically, shortly after acquiring the rights to Thiola, Retrophin raised the product's price from $1.50 per tablet to $30.00 per tablet—an increase of nearly 2,000 percent for a drug that is initially dosed at 3 tablets per day.[36]

59. Later, Shkreli lauded this effort as a case study in "successful transactions"—"Increased price 21x with no pushback from payors."[37]

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[33] Ex. B, Senate Report Hr'g Ex. 18 at 8 (emphasis added).

[34] Ex. B, Senate Report Hr'g Ex. 1 at 1-2.

[35] Ex. B, Senate Report Hr'g Ex. 59 at 5 (emphasis added).

[36] Ex. A, Senate Report at 42.

[37] Ex. B, Senate Report Hr'g Ex. 59 at 3.

60. This conduct drew criticism from doctors and patients, caught the attention of the media, and prompted scrutiny from the government.[38] As noted above, beginning in November 2015, two United States Senators—Senator Susan Collins of Maine and Senator Claire McCaskill of Missouri—led a bipartisan investigation into select companies' drug pricing strategies, including Retrophin's. This investigation involved, among other efforts, three congressional hearings, the review of thousands of documents, and multiple interviews with patients, doctors, industry executives, and consumer advocates. As Senator McCaskill observed, "The hedge fund model of drug pricing is predatory, and immoral for the patients and taxpayers who ultimately foot the bill—especially for generic drugs that can be made for pennies per dose."[39]

61. Even after the congressional investigation into its business practices, Retrophin, in concert with Mission and Alamo, continued to implement, extend, and profit from the unlawful monopoly initially set up under Shkreli's leadership.

62. Other senior executives at Retrophin were also involved in advancing this scheme. Steven Aselage—Retrophin's President and Chief Operations Officer when Shkreli was CEO, and successor CEO following Shkreli's departure—was acutely aware of efforts to prevent generics from obtaining samples. For example, an email to Mr. Aselage demonstrates that Retrophin executives actively monitored purchase orders to ensure that none of the interested purchasers were a "conduit for a generic manufacturer."[40]

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[38] *See, e.g.*, Ariana Eunjung Cha, *Senate launches investigation into drug pricing at 'pharma bro' company Turing, three others*, WASH. POST (Nov. 4, 2015), https://www.washingtonpost.com/news/to-your-health/wp/2015/11/04/senate-launches-investigation-into-drug-pricing-at-pharma-bro-company-turing-three-others/.

[39] *Collins, McCaskill Release Committee Report of Bipartisan Drug Pricing Investigation*, SUSAN COLLINS U.S. SENATOR FOR ME. (Dec. 21, 2016), https://www.collins.senate.gov/newsroom/collins-mccaskill-release-committee-report-bipartisan-drug-pricing-investigation.

[40] Ex. B, Senate Report Hr'g Ex. 37 at 1.

63. In addition, the Agreement has been amended several times since Shkreli's resignation, including a March 2016 amendment to include the new development project for Thiola, and a November 2017 amendment to extend the initial license term through May 2029.

64. Mission, for its part, continues to manufacture and supply Thiola exclusively to Retrophin in exchange for a cut of Retrophin's product sales—benefitting from this anticompetitive distribution scheme. In addition, Mission and Retrophin are working to remove the original Thiola formulation from the market and replace it with a new formulation, on which Mission and Retrophin intend to seek (and/or have already sought) patent protection—a move known as a "hard switch."[41] This potential "product hopping" is yet another effort to artificially and unlawfully extend Retrophin's monopoly.

65. On information and belief, Alamo continues to serve as the exclusive sales force services provider for Thiola, benefitting from Retrophin's anticompetitive distribution scheme.

66. Retrophin's most recent 10-K, filed on February 27, 2018, makes clear that it continues to view generics as a threat to its "sales and profitability," and it continues to operate the closed distribution system in concert with Mission and Alamo. As described above, this scheme has both the intent and effect of precluding any generic firm from acquiring samples of Thiola in sufficient quantities necessary to satisfy FDA-required bioequivalence testing.

67. Furthermore, as described below, each of Retrophin, Mission, and Alamo has refused to sell samples of Thiola to Plaintiff, even at market prices, sacrificing short-term profits to achieve anticompetitive ends.

[41] Ex. B, Senate Report Hr'g Ex. 1 at 3; Retrophin Inc., Annual Report Ex. 10.20 at 1-2 (Form 10-K) (Feb. 27, 2018).

Spring's Efforts to Develop a Generic Version of Thiola

68. Spring Pharmaceuticals, LLC was formed in November 2017 for the specific purpose of bringing to the United States market generic alternatives that would compete with off-patent, but still sole-source and overpriced, brand products that treat rare diseases. Prior to its formation, Spring's founders had selected a generic version of Thiola to be the company's first product.

69. But, before Spring can market any generic version of Thiola, it must receive approval from the FDA that its proposed generic product is indeed "bioequivalent" to Thiola. Such approval is conditioned on bioequivalence testing that requires that Spring obtain samples of Thiola.

70. Accordingly, Spring contacted wholesalers, distributors, pharmacies, and other consultants about procuring Thiola samples. Spring was informed that Thiola was not available in normal distribution channels.

71. Spring turned, then, to the exclusive licensee of the product—Retrophin. On January 17, 2018, Spring submitted a web inquiry through Retrophin's corporate website, noting that it was looking for product information. On January 18, 2018, a Retrophin representative e-mailed Spring and asked for additional details concerning Spring's request. In response, Spring explained that it was seeking Thiola samples for generic drug development, and asked to purchase the samples from Retrophin. Spring received no response from Retrophin to this request.

72. Meanwhile, on January 18, 2018, Spring wrote directly to the drug manufacturer, Mission, informing it that Spring was a generic pharmaceutical company developing a generic version of Thiola. Spring offered to purchase samples of Thiola for use in bioequivalence

testing, and asked what the price would be for such samples. Spring did not receive a response from Mission.

73. On January 19, 2018, Spring faxed a similar letter to a number listed on Retrophin's Thiola web portal, again offering to purchase samples of Thiola for bioequivalence testing. In response, Spring received an email from Retrophin's "direct to patient" specialty pharmacy, stating that it does not make wholesale shipments.

74. Rebuffed by Mission and Retrophin, Spring pursued alternative channels through which it might obtain samples of Thiola. Since January, Spring has tried to acquire Thiola samples from other sources, including two specialty pharmacies with experience acquiring samples of branded pharmaceutical products for interested generic manufacturers, as well as a company that advertised its ability to access an "extended variety" of pharmaceutical products. To date, Spring has not been able to procure Thiola samples from these sources.

75. In June 2018, Spring sent letters via certified mail to Retrophin and Mission again requesting the opportunity to purchase samples of Thiola, and stating its willingness to pay fair market price for them. Once again, Spring received no response.

76. On August 9, 2018, Spring sent a letter to Alamo by certified mail, similar in form to the previous letters sent to Mission and Retrophin—requesting the opportunity to purchase Thiola samples and stating its willingness to pay market prices. Spring received no response.

77. Defendants have each refused to sell the required samples to Spring, even at market prices. With the products removed from the distribution channel, Spring has been unable to conduct the bioequivalence testing necessary to obtain FDA approval, and has thus been excluded from the market.

78. Spring is ready to begin development of its product upon receipt of the Thiola samples. For example, as early as April 2017, the founders of Spring began discussions with pharmaceutical manufacturers, laboratories, and consultants regarding the development of a generic version of Thiola. Spring and/or its founders have also been in negotiations with multiple, experienced contract development and manufacturing organizations ("CDMOs")[42] since August 2017 regarding product development and manufacturing. In connection with those discussions, Spring has reached an agreement with one CDMO to perform the necessary development work once Spring is able to acquire the Thiola samples required to advance the work. This particular CDMO has a track record of success in supporting abbreviated new drug applications, and is ready to commence work on developing a generic version of Thiola. The CDMO's technical team is confident in its ability to develop a bioequivalent product that will be approved by the FDA for the United States market.

79. Spring has also been in discussions with expert consultants who will assist with the necessary regulatory processes that will be required to obtain approval of its generic version of Thiola.

80. Spring has secured financing to bring the generic product to market, sufficient to include product development and regulatory submission. Once the product is approved, Spring also plans to invest in the sales, marketing, and supply of its generic version of Thiola to compete head-to-head with Retrophin, Mission, and Alamo.

[42] CDMOs are specialized service providers that develop and manufacture pharmaceutical products for client companies.

Relevant Product Market and Geographic Market

81. As noted above, Thiola treats patients suffering from cystinuria—a chronic genetic disease that causes recurring kidney stones.

82. On information and belief, cystinuria afflicts about 1 in every 10,000 persons, with approximately 20,000 cases in the United States.

83. In terms of drug treatment for cystinuria in the United States, there are no substitutes for Thiola. Retrophin documents make this clear, characterizing Thiola as the "standard of care" for cystinuria, with the other potential drug product—Cuprimine®—targeted as "inferior" and "toxic" in terms of safety and efficacy.[43] As Retrophin explained to market analysts, Cuprimine is primarily indicated for a different disease, and in any event, "[p]hysicians prefer Thiola over Cuprimine because the adverse event profile for Thiola is better. Cuprimine is a very harsh therapy and patients who are allergic to penicillin are also allergic to penicillamine. Thiola is also believed to be more efficacious[.]"[44]

84. Indeed, the lack of substitutes and the inelasticity of demand is precisely why Retrophin targeted Thiola for its commercial portfolio in 2014. As Shkreli told one investor in early May 2014, "[t]he next generation of pharma guys (or the smart ones) understand the inelasticity of certain products. . . . We'd pay $1m to acquire a drug called Thiola, which is the only treatment for a rare disease called cystinuria."[45]

85. In 2014, Retrophin estimated that there were 300–400 patients who were taking Thiola.[46] In 2015, it claimed that number was greater than 725 patients.[47]

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[43] Ex. B, Senate Report Hr'g Ex. 1 at 1-2.

[44] Ex. B, Senate Report Hr'g Ex. 20 at 1.

[45] Ex. B, Senate Report Hr'g Ex. 10 at 1-2.

[46] Ex. A, Senate Report at 6, tbl. 1.

[47] Ex. C, Retrophin, Inc. Corporate Overview (Summer 2015) at 4.

86. In 2015, Retrophin further estimated that there were an additional 4,000–5,000 candidates for Thiola in the United States.[48]

87. Retrophin reported net product sales of nearly $55 million from Thiola in 2015. Those sales increased to $71 million in 2016, and $82 million in 2017.[49]

88. Thiola is off patent.

89. Thiola is not subject to any other government-provided exclusivity period.

90. Thiola is not subject to a Risk Evaluation and Mitigation Strategies ("REMS") protocol.[50]

91. Pending access to Thiola samples and regulatory approval, the lower-cost, generic tiopronin product developed by Spring would be bioequivalent to Thiola and subject to states' automatic substitution laws.[51]

92. The relevant product market in which to assess the anticompetitive effects of Defendants' conduct is the United States market for FDA-approved tiopronin pharmaceutical products, that is, Thiola and any approved generic version thereof (the "Relevant Market").

93. Courts have recognized that a specific brand product, and a potential generic with the same active ingredient, may constitute the relevant product market for antitrust purposes.

94. The relevant geographic market is the United States of America. On information and belief, Thiola is distributed by Defendants to patients located across the country.

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[48] *Id.* at 9.

[49] Retrophin Inc., Annual Report 46 (Form 10-K) (Feb. 27, 2018).

[50] A REMS protocol is a regulatory protocol implemented by the FDA to restrict access to certain drugs that pose potential safety risks to consumers.

[51] As described *supra*, most states have "automatic substitution" laws, which require or allow pharmacists to substitute the AB-rated generic version for brand products, unless the prescribing physician specifically requests otherwise.

95. Retrophin, as the exclusive licensee of Thiola, is the only company with an FDA-approved tiopronin product. As a result, at all times relevant to this Complaint, Retrophin has possessed a 100% market share in the Relevant Market and, indeed, has complete market dominance in the relevant product and geographic markets.

96. Retrophin maintains this monopoly, in concert with Mission and Alamo, through a closed distribution system, precluding generic entry into the marketplace.

Spring's Damages and Antitrust Injury

97. As detailed above, Spring has exhausted all possible legal sources to acquire the Thiola samples necessary for generic development. As a result of Defendants' exclusionary and anticompetitive conduct, Spring has been prevented from and/or delayed in securing regulatory approval and entering the Relevant Market, causing Spring to lose revenue based on product sales and to incur associated costs and fees. Spring will also be required to pay higher development costs.

98. Absent this anticompetitive refusal to deal, Spring would have entered the Relevant Market much earlier, and secured a large market share with substantial sales through lower prices and effective marketing. Defendants' conduct has deprived Spring of not only future profits, but also the resources Spring has already invested in developing a generic version of Thiola—resources that are wasted if Spring cannot enter the market. Spring has also incurred higher costs because of the delay.

99. The actual and continuing injuries to both Spring and competition flow directly from Defendants' anticompetitive conduct. As described in detail above, Defendants' exclusionary conduct has prevented, and continues to prevent, Spring from entering the market as a generic competitor. By implementing a closed distribution scheme and actively policing

sales and product inquiries to completely eliminate the possibility of generic competitors acquiring the samples of Thiola necessary for bioequivalence testing, Defendants have foreclosed the possibility of generic competition and fortified their monopoly position.

100. If allowed to continue, Defendants' scheme will permanently prevent any generic alternative to Thiola.

101. Defendants' conduct has not only harmed Spring, it has caused substantial harm to the competitive process as well as to individual consumers, health care payers, government payers, and taxpayers, all of whom have been deprived of the primary benefits of competition—equivalent products at lower prices. The anticompetitive effects of Defendants' conduct are evident from the staggering Thiola price increases. Defendants' refusal to deal with potential generic competitors on commercially reasonable terms, coupled with the Thiola price increases, reveal a predatory intent to stifle competition at the expense of consumers.

102. There are no pro-competitive justifications for Defendants' refusal to deal. Their conduct can only be explained by anticompetitive motives, and a desire to foreclose competition in the relevant market. Any proffered justification is mere pretext. As Senator Collins noted in connection with the Senate's investigation into Retrophin's business practices:

> There's absolutely no reason, according to the medical experts that we've talked to, to put this drug into a specialty pharmacy or a restricted distribution system other than to prevent generics from buying up enough of the drug to produce a lower-price generic version. The only exceptions are drugs that have special safety risks. And that is not the case here according to what the experts tell us.[52]

103. Defendants' exclusionary and unlawful conduct has injured Spring, consumers, and patients alike, while Defendants reap supracompetitive profits from an artificial monopoly. This conduct must be stopped.

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[52] Senator Susan Collins, *Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model*, U.S. SENATE SPECIAL COMM. ON AGING, 03:10:18-03:11:00 (Mar. 17, 2016), https://www.aging.senate.gov/hearings/ sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model.

COUNT I
Mandatory Injunctive Relief – All Defendants

104. Spring re-alleges and incorporates by reference paragraphs 1–103 as if fully set forth herein.

105. Defendants' conduct, as outlined above, has directly, proximately, and foreseeably caused irreparable harm to Spring, and continues to threaten immediate and irreparable harm to Spring, including in the following ways:

a. Spring cannot access sufficient quantities of Thiola to conduct bioequivalence testing necessary to enter the Relevant Market;

b. Spring has expended and will expend substantial sums to access Thiola samples, including through the present litigation;

c. Spring will pay higher development costs as a result of its delayed entry into the Relevant Market;

d. Spring stands to lose substantial profits from lost sales by virtue of its foreclosure from and/or delayed entry into the Relevant Market.

106. Defendants' conduct, as outlined above, has also injured or threatens injury to competition by monopolizing and maintaining monopoly power, creating artificial barriers to entry, and precluding generic competition in the Relevant Market.

107. The irreparable harm to Spring and to competition threatened and/or caused by Defendants' conduct cannot be fully remedied by money damages because Spring needs Thiola samples in order to conduct the required bioequivalence testing before entering the Relevant Market.

108. Spring does not have an adequate remedy at law because only injunctive relief will ensure the provision of sufficient amounts of Thiola necessary for Spring to conduct bioequivalence testing.

109. Granting the requested injunctive relief to Spring will not result in greater hardship to Defendants, as Spring would be purchasing the Thiola samples at market prices.

110. Granting the requested injunctive relief to Spring will be in the public interest, as it will facilitate generic drug development, foster competition, and improve the affordability of and access to vital health products.

111. Spring requests and is entitled to an injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, requiring Defendants to permit Spring to purchase samples of Thiola at market price for bioequivalence testing.

COUNT II
Sherman Act Section 2
Monopolization and/or Attempted Monopolization – Retrophin

112. Plaintiff re-alleges and incorporates by reference paragraphs 1–111 as if fully set forth herein.

113. As detailed above, Retrophin has monopoly power in the Relevant Market, including the power to control prices. This complete monopoly will remain in place unless and until it is contested by a bioequivalent FDA-approved generic alternative reaching the market.

114. As alleged herein, Retrophin has willfully and intentionally engaged in anticompetitive conduct in order to unlawfully acquire and maintain its monopoly in the Relevant Market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and similar state laws.

115. Specifically, Retrophin has unlawfully monopolized the Relevant Market through, among other anticompetitive acts:

a. Entering into exclusive dealing contracts with Defendants Mission and Alamo;

b. Moving Thiola into a restricted distribution system designed to exclude generic competition;

c. Actively monitoring orders to ensure that generic manufacturers do not obtain necessary product samples;

d. Extending the monopoly through contract amendments;

e. Artificially seeking to extend the monopoly through "product hopping" efforts;

f. Refusing to sell necessary samples to a generic manufacturer at market prices; and

g. Failing to negotiate on commercially reasonable terms.

116. Retrophin's conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

117. As a direct, foreseeable, and proximate result of Retrophin's anticompetitive and monopolistic conduct, Spring has suffered commercial and competitive injuries, with resultant damages in amounts to be proven at trial, including at least in the following ways: (i) Spring has been foreclosed, or at the very least delayed, from competing in the Relevant Market; (ii) Spring has lost revenue from lost product sales and business opportunities; and (iii) Spring has incurred significant costs and fees.

118. As a direct, foreseeable, and proximate result of Retrophin's anticompetitive and monopolistic conduct, the competitive process as well as individual patients and payors in the Relevant Market have been harmed by, among other things, (i) Retrophin's ability to charge supra-competitive prices for Thiola, and (ii) reduced choice and diminished access to effective drug treatments.

119. Spring will continue to lose sales and profits, and consumers will continue to suffer from the lack of generic price competition, if Retrophin's unlawful conduct is not

enjoined. Spring has been directly harmed and has suffered direct antitrust injury by Retrophin's anticompetitive and monopolistic conduct and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

120. In the alternative, Retrophin has denied access to essential goods, services, or resources necessary to compete in the Relevant Market, constituting a violation of Section 2.

121. As detailed above, Retrophin has monopoly control over Thiola. Thiola is an essential resource for FDA-required bioequivalence testing. Retrophin's distribution of Thiola, thus, is an essential facility for the development and production of the generic version of Thiola.

122. Spring is practicably unable to procure these samples from an alternate source, to reasonably duplicate the product, or to otherwise conduct the testing necessary to file an abbreviated new drug application for its generic version of Thiola.

123. It would be feasible for Retrophin to provide the Thiola samples on commercially reasonable terms.

124. By implementing a closed distribution system and refusing to provide Spring with essential samples, despite Spring's willingness to pay market prices, Retrophin has denied access to an essential resource and has wrongfully maintained its monopoly power with respect to Thiola, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

125. Retrophin has no pro-competitive, legitimate business justification for sacrificing profits by refusing to sell samples of Thiola to Spring on commercially reasonable terms. Its conduct can be explained only by anti-competitive motives, including the desire to thwart generic competition in the Relevant Market.

126. Courts have recognized that a brand drug manufacturer's refusal to deal with, and/or provide necessary samples to, a generic drug manufacturer may give rise to liability under the essential facilities doctrine.

127. As a result of Retrophin's unlawful denial of access to an essential facility or resource, Spring has suffered and will continue to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

128. As a result of Retrophin's unlawful denial of access to an essential facility or resource, the competitive process has suffered, and will continue to suffer. In particular, competition in the Relevant Market will continue to be restrained and foreclosed. The lack of competition will deprive patients and payors of its primary benefits—more choices and lower prices.

129. Spring has been directly harmed and has suffered direct antitrust injury by Retrophin's unlawful denial of access to an essential facility or resource and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

130. Spring requests and is entitled to a judgment that Retrophin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Retrophin's continued violations.

COUNT III
Sherman Act Section 2
Conspiracy to Monopolize – All Defendants

131. Plaintiff re-alleges and incorporates by reference paragraphs 1–130 as if fully set forth herein.

132. As detailed above, Retrophin has monopoly power in the Relevant Market, including the power to control prices. This complete monopoly will remain in place unless and until it is contested by a bioequivalent, FDA-approved, generic alternative reaching the market.

133. As alleged herein, Defendants Shkreli, Retrophin, Mission, and Alamo entered into exclusive agreements with the specific intent to monopolize the Relevant Market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and similar state laws.

134. Each Defendant also took overt acts in furtherance of this conspiracy.

135. Defendant Shkreli instituted the complained-of unlawful scheme: causing Retrophin to acquire rights in an off-patent, decades-old drug, with the specific intent to move the drug into a restricted distribution scheme designed to prevent generic entry, and to thereafter set and preserve monopoly-level prices, causing harm to potential competitors and consumers.

136. Shkreli and Retrophin accomplished this scheme by entering into exclusive agreements with Mission and Alamo—entities that stood to profit from, and in fact perpetuated, the unlawful contractual and distribution scheme, even after Shkreli's departure, and even after media and governmental scrutiny of Retrophin's business practices.

137. Most recently, by means of their refusal to provide essential samples to Spring, each of Retrophin, Mission, and Alamo has acted for the specific purpose of, and in furtherance of, monopolizing the Relevant Market.

138. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

139. As a direct, foreseeable, and proximate result of Defendants' conspiratorial and anticompetitive conduct, Spring has suffered commercial and competitive injuries, with resultant damages in amounts to be proven at trial, including at least in the following ways: (i) Spring has been foreclosed, or at the very least delayed, from competing in the Relevant Market; (ii) Spring has lost revenue from lost product sales and business opportunities; and (iii) Spring has incurred significant costs and fees.

140. As a direct, foreseeable, and proximate result of Defendants' conspiratorial and anticompetitive conduct, the competitive process as well as individual patients and payors in the Relevant Market have been harmed by, among other things, (i) Defendants' preservation of supra-competitive prices for Thiola, and (ii) reduced choice and diminished access to effective drug treatments.

141. Spring will continue to lose sales and profits, and consumers will continue to suffer from the lack of generic price competition, if Defendants' unlawful conduct is not enjoined. Spring has been directly harmed and has suffered direct antitrust injury by Defendants' anticompetitive and monopolistic conduct and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

142. In the alternative, Defendants have conspired to deny access to essential goods, services, or resources necessary to compete in the Relevant Market, constituting a violation of Section 2.

143. As detailed above, Thiola is an essential resource for FDA-required bioequivalence testing. Defendants' distribution of Thiola, thus, is an essential facility for the development and production of a generic version of Thiola.

144. Spring is practicably unable to procure these samples from an alternate source, to reasonably duplicate the product, or to otherwise conduct the testing necessary to file an abbreviated new drug application for its generic version of Thiola.

145. It would be feasible for Defendants to provide the Thiola samples on commercially reasonable terms.

146. By instituting and preserving a closed distribution system designed to prevent generic entrants, and by refusing to provide Spring with essential Thiola samples, despite Spring's willingness to pay market prices, Defendants have conspired to deny access to an essential resource, allowing Retrophin to unlawfully maintain its monopoly power with respect to Thiola, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

147. Defendants have no pro-competitive, legitimate business justification for sacrificing profits by refusing to sell samples of Thiola to Spring at market prices. Their conduct can be explained only by anti-competitive motives, including the desire to thwart generic competition in the Relevant Market.

148. As a result of Defendants' unlawful denial of access to an essential facility or resource, Spring has suffered and will continue to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

149. As a result of Defendants' unlawful denial of access to an essential facility or resource, the competitive process has suffered, and will continue to suffer. In particular, competition in the Relevant Market will continue to be restrained and foreclosed. The lack of

competition will deprive patients and payors of its primary benefits—more choices and lower prices.

150. Spring has been directly harmed and has suffered direct antitrust injury by Defendants' unlawful denial of access to an essential facility or resource and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

151. Spring requests and is entitled to a judgment that Defendants have conspired to violate Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT IV
Sherman Act Section 1
Contract in Restraint of Trade – All Defendants

152. Plaintiff re-alleges and incorporates by reference paragraphs 1–151 as if fully set forth herein.

153. As detailed above, and through the foregoing acts, Defendants entered into a continuing contract, combination, or conspiracy to unreasonably restrain trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by artificially reducing or eliminating competition in the Relevant Market.

154. Specifically, beginning in May 2014 and continuing through to the present, Defendants acted in concert to thwart competition in the Relevant Market by entering into—and continuing to amend and prolong—an exclusive licensing agreement, and corollary services agreement, in furtherance of Shkreli and Retrophin's anticompetitive business model.

155. These exclusionary agreements are unreasonably restrictive in terms of duration and market coverage, as they impede the supply and sale of Thiola and serve the anticompetitive purpose of precluding generic competition in the marketplace.

156. Pursuant to these agreements, Mission and Alamo continue to profit from, and participate in, the exclusionary and unlawful distribution scheme initially devised by Shkreli and, to this day, perpetuated by Retrophin in concert with Mission and Alamo.

157. The anticompetitive effects of this concerted conduct are clear: generic entrants are precluded from entering the marketplace, and patients and payors are deprived of lower-cost, generic alternatives to Thiola.

158. Defendants' unlawful and concerted conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

159. As a result of Defendants' unlawful and concerted conduct, effectuated through exclusive and unjustified agreements, Spring has suffered and will continue to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

160. Spring requests and is entitled to a judgment that Defendants' exclusionary and concerted conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT V
Pennsylvania State Law of Unfair Competition – All Defendants

161. Plaintiff re-alleges and incorporates by reference paragraphs 1–160 as if fully set forth herein.

162. In violation of the common law of the State of Pennsylvania, Defendants unfairly competed with Spring by entering into, and continuing, an exclusive and unlawful business arrangement designed to impede generic competition and to artificially preserve a monopoly at the expense of consumer health and welfare. Defendants also unfairly competed with Spring by refusing to sell necessary Thiola samples to Spring despite its willingness to pay market prices.

163. Defendants' conduct constitutes unfair competition because it violates standards of commercial morality and has substantially interfered with Plaintiff's ability to compete on the merits of its product, and otherwise conflicts with accepted principles of public policy recognized by antitrust laws and other common law.

164. Defendants' unfair competition occurred in a course of conduct involving trade or commerce.

165. Spring suffered actual damages that were proximately caused by Defendants' unfair competition, including for the reasons set forth above.

COUNT VI
Common Law Unjust Enrichment – All Defendants

166. Plaintiff re-alleges and incorporates by reference paragraphs 1–165 as if fully set forth herein.

167. As detailed above, and through the foregoing acts, Defendants unjustly retained a benefit to Spring's detriment, including the benefit of artificial and unlawful protection from the competitive process.

168. Under the common law of the State of Pennsylvania, Defendants' retention of these benefits violates the fundamental principles of justice, equity, and good conscience.

169. Spring requests and is entitled to a disgorgement of the benefit conferred upon Defendants by virtue of their unlawful and exclusionary conduct.

RELIEF REQUESTED

WHEREFORE, for the foregoing reasons, Plaintiff Spring Pharmaceuticals, LLC respectfully requests that this Court enter an order for Plaintiff and against Defendants, granting Plaintiff the following relief:

(a) Compelling Defendants to sell Plaintiff sufficient quantities of Thiola at market prices so that Plaintiff may conduct bioequivalence testing;

(b) Awarding Plaintiff damages for losses suffered as a result of Defendants' actions in an amount to be proven at trial, including, but not limited to, compensatory damages for Plaintiff's lost sales and profits on its generic version of Thiola, and the disgorgement of any benefit unlawfully retained;

(c) Awarding Plaintiff treble damages pursuant to 15 U.S.C. § 15, along with all other available statutory damages, with interest;

(d) Awarding Plaintiff its costs and expenses, including attorneys' fees and costs; and

(e) Granting Plaintiff such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Spring Pharmaceuticals, LLC demands a trial by jury as to all issues of right to a jury.

Respectfully submitted,

SPRING PHARMACEUTICALS, LLC

Date: October 23, 2018

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